

REMARKS

Claims 161-166, as amended, and new claims 261-279 are pending in the instant application. Applicant notes with appreciation the Examiner's allowance of claims 161-164. Claims 124-160 and 167-260 have been cancelled without prejudice. Applicants reserve the right to pursue these claims in a continuing or divisional application. Claims 161, 165 and 166 have been amended to more particularly point out and distinctly claim the subject matter of the present invention.. New claims 261-279 have been added. Support for the new claims and amendments can be found throughout the specification. No new matter is added.

I. Rejections Under 35 U.S.C. § 112

Claims 248-250, 252-254 and 256-258 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner stated that claims 252-254 have no antecedent basis in base claim 141, drawn to a zolpidem hemitartrate solvate, claims 248-250 have no antecedent basis in base claim 124, drawn to a zolpidem hemitartrate hydrate, and claims 256-258 have no antecedent basis in base claim 149, drawn to an anhydrous zolpidem hemitartrate.

In order to expedite prosecution of the instant application, Applicants have cancelled claims 248-250, 252-254 and 256-258. Applicants, therefore, respectfully submit that these grounds for rejection have been rendered moot, and should be withdrawn.

II. Rejections Under 35 U.S.C. § 103(a)

(a). Claims 124-127, 14[sic], 142 and 166 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,281,360 to Ettema et al. ("Ettema I") in view of U.S. Patent No. 6,242,460 to Ettema et al. ("Ettema II"). Applicants have canceled claims 124-127 and 141-142. Claim 166 has been amended to depend from claim 161. Claim 161 was allowed by the Examiner, thus Applicants believe that dependant claim 166 is allowable.

(b). Claims 139, 140, 147, 148, 247-258 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ettema I in view of Ettema II, and further in view of U.S. Patent No. 5,271,944 to Lee ("Lee") and/or U.S. Patent No. 4,332,721 to Bernini ("Bernini"). Applicants have cancelled claims 139, 140, 147, 148, 247-258, and, therefore, respectfully submit that this ground of rejection is rendered moot.

(c). Claims 124-127, 141, 142 and 166 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,891,891 to Benincasa, ("Benincasa") in view of U.S. Patent No. 4,382,938 to Kaplan, ("Kaplan") and "Pharmaceutical Applications of Drug Crystal Studies," G. Michael Wall, Pharmaceutical Manufacturing, Vol. 3, No. 2, February 1986 ("Wall"). Applicants have canceled claims 124-127 and 141-142. Claim 166 has been amended to depend from claim 161. Claim 161 was allowed by the Examiner, thus Applicants believe that dependant claim 166 is allowable.

(d). Claims 139, 140, 147, 148 and 247-258 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Benincasa in view of Kaplan and Wall, and further in view of Lee and/or Bernini. Applicants have cancelled claims 139, 140, 147, 148 and 247-258, and, therefore, respectfully submit that this ground of rejection is rendered moot.

III. Rejection Under 35 U.S.C. § 102(b)

Claims 165, 247-258 were rejected as unpatentable under 35 U.S.C. § 102(b) as allegedly anticipated by Benincasa. Applicants have canceled claims 247-258. Claim 165 has been amended to depend from claim 161. Claim 161 was allowed by the Examiner, thus Applicants believe that dependant claim 165 is allowable. Applicants, therefore, respectfully traverse the rejection as applied to claim 165.

Further, claim 165, as amended, recites that the pharmaceutical composition comprises a therapeutically effective amount of the zolpidem hemitartrate polymorph of the instant invention, wherein the zolpidem hemitartrate is in the form of particles having a size of up to about 200 microns. Support for this amendment may be found, *inter alia*, at page 24, lines 16-18. Applicants respectfully submit that the Examiner's comment that "the optionally micronized hydrate or solvate form of the instant would no longer exist in solution" is, therefore, rendered moot.

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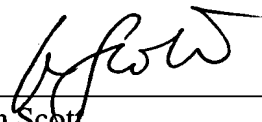
CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 161-166 and 261-279 are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at the number below.

No fee beyond that due for the extension of time is believed due for the submission of this response. The Commissioner is authorized to charge any required fees that may be due to Deposit Account No.11-0600.

Respectfully Submitted,

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Ian Scott
Reg. No. 44,327

KENYON & KENYON
One Broadway
New York, NY 10004

Tel: (212) 425-7000
Fax: (212) 425-5288

Appendix A
Marked Up Versions of Amended Claims

161. (Amended) Zolpidem hemitartrate [Form D], characterized by an X-ray powder diffraction pattern having peaks at about 7.1, 9.5, 14.1, 19.6 and 24.5 ± 0.2 degrees two-theta.

165. (Amended) A pharmaceutical composition comprising a therapeutically effective amount of the zolpidem hemitartrate of claim 161, wherein the zolpidem hemitartrate is in the form of particles, and a pharmaceutically acceptable carrier.

166. (Amended) A method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate [Form D] of claim 161.